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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,529	11/07/2001	Mitchell D. Eggers	PW 083022 272516	9202

7590 06/30/2005

Pillsbury Winthrop LLP
Intellectual Property Group
50 Fremont Street
P.O. Box 7880
San Francisco, CA 94105

EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,529

Applicant(s)

EGGERS, MITCHELL D.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74,77,78,80,84-91,94-111,114 and 115 is/are rejected.
- 7) ☒ Claim(s) 75,76,81-83,92,93,112 and 113 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

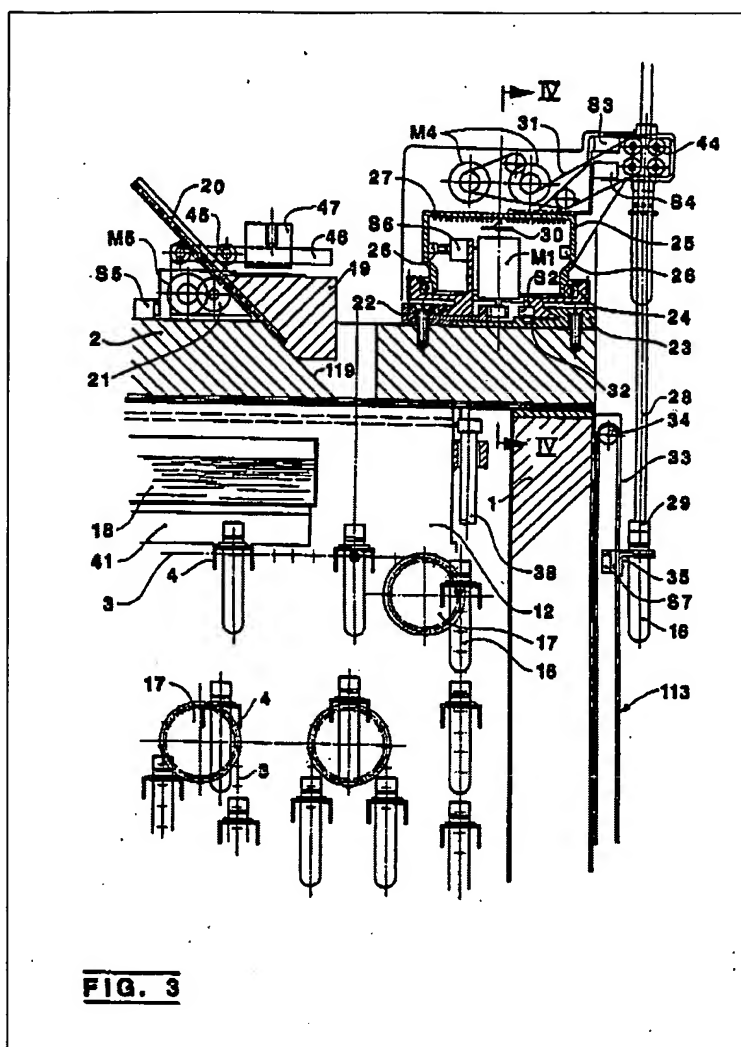
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36 – 38, 40 – 43, 45 – 49, 51 – 55 & 57 – 62 are rejected under 35

U.S.C. 102(b) as being anticipated by Knippscheer et al. (U.S. Pat. No. 5,125,240 A). Regarding claims 34, 38, 45, 46 and 55, Knippscheer et al. teach a method of archiving samples, wherein the method comprises the steps of: selectively transferring a specimen (e.g., contained in ampule 16) obtained from a source, to a plurality of discrete sample nodes (support bars 4) attached to a sample carrier (conveyor chains 3); archiving the sample carrier in an archive facility (container 18); and recording the location of the sample carrier in the archive facility utilizing a computer (CC1) (see col. 5, line 20 – col. 8, line 60; figures 1 – 3). Regarding claims 36, 37, 45, 53 and 54, Knippscheer et al. teach the use of barcoding indicia (see col. 2, lines 53 – 64; col. 9, lines 21 – 31). Regarding claims 40 and 57, the cryogenic process acts as a preservative agent for the samples (see col. 1, lines 15 – 37). Regarding claims 41 – 43 and 47 – 49, the process may be utilized to store biological samples, which are inherently anticipated to comprise protein, polynucleotide or DNA materials (see col. 1, lines 15 – 37) (see MPEP § 2112, see also MPEP § 2144.03). Regarding claim 51, since, for example, Knippscheer et al. teach that their disclosed process is utilized in archiving and storing frozen umbilical cord blood from individuals, it is inherently anticipated that consent would be required to obtain the specimens (see col. 15, line

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58 – col. 19, lines 48) (see MPEP § 2112, see also MPEP § 2144.03). Regarding claim 52, it is inherently anticipated that the apparatus would be washed or sterilized prior to storing and archiving a biological sample in order to avoid the transmission of infectious diseases between patient samples (see MPEP § 2112, see also MPEP § 2144.03). Regarding claim 58, Knippscheer et al. teach the use of a computer, which utilizes a computer readable medium, such as a computer memory device, containing an executable instructional code in the executing of the methodology, as discussed above (see col. 10, lines 22 – 47). Regarding claims 59 – 62, Knippscheer et al. teach the transmission of information to and from remote device during operation at an archive facility, such as an information storage facility or a central computer facility via telephone, wireless or satellite communications (see col. 13, line 63 – col. 14, line 54).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

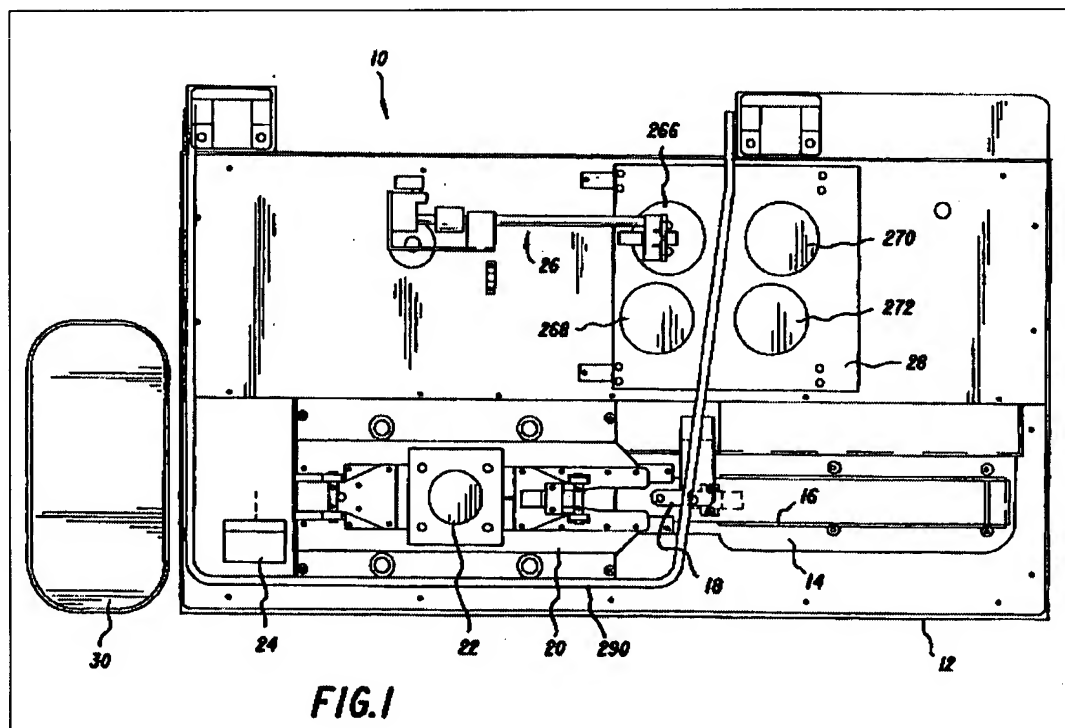
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 3 – 9, 11 – 22, 24 – 28, 30 – 32, 63 – 66, 70, 71, 73, 74, 77 – 80, 87, 88, 90, 91, 94, 96 – 99, 101 – 105, 107, 108, 110, 111, 114, & 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehan (U.S. Pat. No. 5,800,777 A). Regarding claims 1, 6, 16, 28, 32 and 94, Jehan teaches a sample archive system (10) comprising: a sample carrier (sample magazine 16) configured to support a plurality of sample nodes (samples 42) in a predetermined spatial relationship; sample storage means (sample magazine receptacle 14) for selectively placing the plurality of sample carriers in an archive; and a sample node removal means (sample acquisition system 18 & transport system 20), which constitutes a robotic means, for locating and removing selected sample nodes (see figure 1; col. 5, lines 25 – 66). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and*

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Lomb, Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Jehan does not specifically teach the utilization of a plurality of sample carriers (sample magazine 16). The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a plurality of sample carriers (sample magazine 16).



Regarding claims 3, 11, 20, 32 and 96, Jehan teaches the incorporation of a sample node removal means comprising a mechanical clipping tool, such as a sample punch mechanism (22)

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(see col. 8, lines 40 – 67). Regarding claims 4, 12, 17, 18 and 97, Jehan teaches the incorporation of an optical reflection sensor (e.g., sensor 16 or 86) for sample location detection (see col. 6, lines 26 – 67; col. 7, lines 1 – 9). Regarding claims 5, 13, 19, 98 and 101, Jehan teaches the incorporation of an associated positioning component (e.g., a function served by the sample acquisition system 18 & transport system 20) responsive to the optical reflection sensor (see col. 7, lines 10 – 56). Regarding claims 7, 8, 25 and 26, Jehan anticipates that the sample magazine (16) typically forms a vertical stack, which is functionally equivalent to a rack or drawer for holding samples (see col. 5, lines 45 – 60). Regarding claims 9 and 27, Jehan teaches the incorporation of a bar code reader (see, e.g., col. 8, lines 20 – 39). Regarding claims 14 and 30, Jehan teaches the use of a processing means, such as a spectrometer, for processing or analyzing the sample supported on the sample nodes (see col. 9, lines 11 – 43; col. 12, line 39 – col. 15, line 26). Regarding claims 15, 31 and 99, Jehan teaches the incorporation of a controller, such as a system computer (500) (see col. 12, line 39 – col. 13, line 65). Regarding claims 21 and 24, Jehan teaches the incorporation of a sample node locator or sample sensor (150) or optical sensor (116) (see col. 7, lines 10 – 56; col. 8, lines 20 – 39). Regarding claim 22, Jehan anticipates that the punch mechanism is responsive to a sensing mechanism (see col. 9, lines 1 – 10). Regarding claims 63 and 77, as discussed above, Jehan teaches a system for sample archiving and analysis. Jehan also anticipates an associated method of preparing an archive sample for analysis, wherein the method comprises the steps of: receiving a request for related to an experiment, such as for spectrometry; identifying a sample to be analyzed; responsive to the identifying step, ascertaining a location of the sample on a discrete sample node supported by a sample carrier; responsive to the ascertaining step, removing the discrete sample node from the

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sample carrier; and preparing the sample for analysis, such as by spectrometry (see col. 5, line 25 – col. 16, line 16). Regarding claims 64 and 78, Jehan teach that the step of identifying a sample to be analyzed utilizes a step of interrogating a data structure or computer (see, e.g., col. 12, lines 39 – 67). Regarding claim 65, 66, 79 and 80, Jehan anticipates the use of an optical or bar code reader (see col. 12, lines 39 – 67). Regarding claims 70, 83 and 87, as discussed above, Jehan teaches the use of a sample node removal means comprising a mechanical clipping tool, such as a sample punch mechanism (22) (see col. 8, lines 40 – 67). Regarding claims 71 and 88, Jehan teaches the use of a sample container or cup (174) (see col. 9, lines 11 – 43). Regarding claim 73, 74, 90, 91, 110, 111, 114 & 115, the method is employed in analyzing nonbiological and biological samples, such as photographic film and paper products, which contain wood fiber, respectively (see MPEP § 2144.03). Regarding claims 102 – 105, 107, 108, 114 and 115, as discussed above, Jehan teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).

2. Claims 2, 10, 29, 33, 69, 86, 95, 100 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehan in view of Rosenthal et al. (U.S. Pat. No. 5,516,487 A).

Although Jehan does teach the use of a punch mechanism for acquiring samples for testing, Jehan does not specifically teach the incorporation of a laser cutting mechanism. However, Rosenthal et al. do teach the use of a laser cutting mechanism in sample preparation (see col. 3, lines 46 – 63; col. 5, lines 31 – 36). Therefore, as evidenced by Jehan and Rosenthal et al., a person of ordinary skill in the art would have recognized that both of these cutting mechanism

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are functional equivalents (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the laser cutting mechanism disclosed by Rosenthal et al. with the system of Jehan for facilitating effective sample node removal.

3. Claims 23, 67, 68, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehan in view of Issacman et al. (U.S. Pat. No. 6,127,928 A). Jehan does not specifically teach the incorporation of transceiver with each of the sample nodes. Issacman et al. teach the use of RFID transceiver system in tracking objects. The use of RFID tags are considered functionally equivalent to other means of tracking the locations and identifications of objects, such as through the use of bar code indicia (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of an RFID transceiver tracking

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system, as taught by Issacman et al., with the system of Jehan, to facilitate effective sample node tracking.

4. Claims 35, 39, 44, 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knippscheer et al. Regarding claims 35, 39, and 56, Knippscheer et al. do not specifically teach a washing or desiccation or drying step. However, since Knippscheer et al. disclose that their system is utilized in storing biological specimens, such as human organs and umbilical cord segments, it would have been obvious to a person of ordinary skill in the art to incorporate a washing or desiccation step prior to sample transfer using the apparatus (see MPEP § 2144.03). Regarding claims 44 and 50, it would have been obvious to a person of ordinary that the disclosed method would be amenable to specimens containing nonbiological materials, such as buffer solutions (see MPEP § 2144.03).

5. Claims 72, 89 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jehan. Jehan does not specifically teach a washing step. Jehan does teach that the disclosed system is utilized in analyzing photographic film and paper products. It would have been obvious to a person of ordinary skill in the art to incorporate a washing step for the sample prior to analysis in order to facilitate an accurate sample analysis (see MPEP § 2144.03).

Allowable Subject Matter

Claims 75, 76, 81 – 83, 92, 93, 112 & 113 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

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Regarding claims 75, 76, 92, 93, 112 & 113, the cited prior art neither teach nor fairly suggest that the methodology of the cited prior art incorporate the use of polynucleotide amplification in analyzing a sample comprising a polynucleotide.

Regarding claim 81, the cited prior art neither teach nor fairly suggest that the methodology further incorporate a detection step comprising obtaining video signals from an optical sensor.

Response to Arguments

Applicant's arguments filed 4/6/2005 have been fully considered, but they are not persuasive.

It is well settled that the United States Patent and Trademark Office (PTO) is obligated to give a disputed claim term its broadest reasonable interpretation, taking into account any enlightenment by way of definitions or otherwise found in the specification. See *In re Bigio*, 381 F.3d 1320, 1324, 72 USPQ2d 1209, 1211 (Fed. Cir. 2004) (“[T]he PTO gives a disputed claim term its broadest reasonable interpretation during patent prosecution.”). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); *In re Barr*, 170 USPQ 330 (CCPA 1971). The applicant cannot read limitations set forth in the description into the claims for the purpose of avoiding the art. See *In re Sporck*, 155 USPQ 687 (CCPA 1967). The claims must be given their broadest reasonable interpretation consistent with the supporting description. See *In re Hyatt*, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). “The PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art.” See *In re Morris*, 127

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F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). “During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.” See *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). “The PTO broadly interprets claims during examination of a patent application since the applicant may ‘amend his claim to obtain protection commensurate with his actual contribution to the art.’”(quoting *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550 (CCPA 1969)). See *In re Yamamoto*, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984).

Regarding the interpretation of the recited feature “node” in the pending claims, applicant’s specification discloses that “sample nodes 529 may be embodied in paper or cellulose, polystyrene, plastic, or other suitable support material constructed and operative to serve as a long-term storage mechanism for biological or other sample in a desiccated form.” (see p. 33, lines 2 – 8). The specification additionally states that “[t]he present disclosure is not intended to be limited by the shape, size, or dimensional characteristics of sample nodes 529.” (see p. 32, lines 19 – 28). The specification further indicates that the present disclosure is not to be construed to be limited to any specific embodiment for the sample nodes, which comprise the sample support medium (see p. 33, lines 9 – 27). The applicant is advised that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness and precision. See *Teleflex Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002); *Rexnord Corp v. Laitram Corp.*, 60 USPQ2d 1852, 1854 (Fed. Cir. 2001). Exemplification is not considered an explicit definition (see MPEP § 2111.01). Therefore, a sample support medium comprising a “node” can be reasonably interpreted as being a structure for holding a test sample, such as sample well in a microtiter plate, test tube or other container

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apparatus, such as an ampule, which can support or hold a sample, and in particular a desiccated sample, as would be understood by a person of ordinary skill in the art. The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). Although the apparatus as taught by the prior art may not be what the applicant intends as their claimed invention, the claims still encompass the teachings of the prior art. Therefore, the claims still do not exclude the teachings of the prior art.

Regarding the newly amended recitation that “each of the plurality of sample nodes comprising a sample support medium operative to carry a discrete sample in desiccated form,” this recitation is considered an intended use or process limitation. Claim phrases that employ phrases of the type: “adapted to,” “capable of,” “sufficient to,” “operative to,” or “for” doing something, are typical of claim limitations which may not distinguish over the prior art. It has been held that the recitation that an element is “adapted to,” or is “operative to” perform or is “capable of” performing a function is not a positive limitation, but only requires the ability to so perform. Furthermore, the method claims do not positively recite that the samples being processed are desiccated. The method claims recite that the apparatus utilized is capable of, but not limited to, carrying discrete samples in a desiccated form..

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'BS' with a stylized flourish.